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EXTRAORDINARY

भाग II—खण्ड 3—उपखण्ड (ii)

PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके ।

Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF PETROLEUM AND CHEMICALS

ORDER

New Delhi, the 20th September 1967

S.O. 3416.—In exercise of the powers conferred by sub-section (1) read with clauses (c) and (e) of sub-section (2) of section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following Order further to amend the Drugs Prices (Display and Control) Order, 1966, namely :—

1. (1) This Order may be called the Drugs Prices (Display and Control) Third Amendment Order, 1967.

(2) It shall come into force at once.

2. In the Drugs prices (Display and Control) Order, 1966,—

(i) after paragraph 6, the following paragraphs shall be inserted, namely :—

"6A. *Form for obtaining approval of the Central Government.*—For the purpose of obtaining the approval of the Central Government under paragraphs 3 and 6, the manufacturer, importer or distributor of a drug shall supply in the Form appended to this Order all relevant particulars in respect thereof to the Central Government.

6B. *Paragraph 6 not to apply to certain drugs.*—(1) Where a new drug, not included in the price-lists published by any manufacturer, importer or distributor of drugs immediately before the enforcement of this Order, has improved therapeutic value either by incorporation of at least one new therapeutic ingredient developed by original research

or by adoption of manufacturing techniques evolved by appreciable development research, the manufacturer, importer or distributor of such new drug may, after supplying in the Form appended to this Order all relevant particulars in respect thereof in the Central Government, introduce such new drug for sale or include the price of such new drug in his price-list.

(2) The Central Government may, after due scrutiny of the particulars received by order, fix a price for the new drug other than the price included by the manufacturer, importer or distributor of drugs in the price-list referred to in sub-paragraph (1) and thereupon the price of the new drug shall, with effect from such date (not earlier than the date of communication of the order of the Central Government), as may be specified in the Order stand modified accordingly:

Provided that where no such order is made by the Central Government within a period of four months from the date of receipt of the relevant particulars referred to in sub-paragraph (1), the price of the new drug shall be deemed to be the price of such drug as included by the manufacturer, importer or distributor of drugs in his price-list referred to in the said sub-paragraph.

Explanation.—A mere change in dosage or formulation in the preparation of a drug the price of which has been included in the price-list published by any manufacturer, importer or distributor of drugs immediately before the enforcement of this Order, shall not be deemed to constitute a new drug within the meaning of sub-paragraph (1).

(3) Where a question arises whether a drug constitutes a new drug within the meaning of sub-paragraph (1), it shall be decided by the Central Government."

(ii) after paragraph 11, the following Form shall be inserted, namely:—

"FORM

Particulars to be furnished under paragraphs 6A and 6B

[*See* paragraphs 6A and 6B of the Drugs Prices (Display and Control) Order, 1966]

NOTE.—(i) Please fill a separate form for each drug.

(ii) Please enclose a copy of the latest price list of your company if you have not sent one to the Government already. If a copy has already been sent give reference in the forwarding memo.

PART I

1. Name of the company and address of the registered office and factory.

2. Name of the drug [Please indicate also the generic name/chemical name of the active ingredient(s)].

3. Type, composition, and specification of pack.

4. (a) Is the drug claimed to be a new drug as defined in paragraphs 6B of the Control Order? If so, furnish particulars in Part II.

(b) If it is not a new drug, as above, is it a drug proposed to be introduced by you as an addition to your list?

(c) (i) Is the drug already included in your price list, for which a price revision is now sought?

(ii) If so, indicate—

(a) the type composition and specification of pack under which it is being marketed by you.

(b) the date of its introduction

(c) the existing prices (wholesale and retail)

(d) the basis on which these prices were fixed

(e) number and date of Government Order, if any, approving these prices.

5. Give the following details in respect of comparable drugs in the market. (If there is more than one comparable drug, please furnish details of each of the drug):—

Sl. No.	Name of the drug	Name of the manufacturer	Type, composition & pack under which marketed	Approx date of introduction	Wholesale price	Retail price
1	2	3	4	5	6	7

6. The wholesale and retail prices for which approval is sought (furnish particulars in Part III)

7. What was the percentage of sales of this drug to the total turnover of your company during the las two years?

PART II

[To be filled in for 'new drug' referred to in paragraph 6B of the Drugs Prices (Display and Control) Order, 1966]

1. Does it contain a new therapeutic ingredient developed by original research? If so, give the chemical and generic name of the ingredient.

2. Has there been any scientific publication about the new ingredient? If so, enclose a copy of the publication.

3. Is the new ingredient, the subject of any patent? If so, give details.

4. Has any developmental work/research been carried out for the evolution of the drug? If so, give details.

5. Is there any medical literature about the drug? If so, enclose copies.

6. Indicate the specific advantages of this drug over any existing comparable drugs in the market.

7. Give details of the trials carried out to substantiate the claims.

8. Has approval under the Drugs Act if necessary, been obtained for the introduction of this drug?

9. Has this drug been introduced in any country? If so, give particulars.

PART III

Cost and price data

NOTE.—(i) Please fill this Part separately for each pack.

(ii) In the case of revision of price of existing drugs, please fill in this part to give the particulars valid for

(1) 1963 or the date on which the price revision proposal was earlier accepted by Government;

(2) 30-6-1966; and

(3) the date of present claim for price revision.

A. Specification of the pack

B. Ex-factory cost :	Unit	Cost to factory per unit	Quantity consumed	Total cost
		Rs.		Rs.
(i) Cost of materials:				
(a) Imported* (specify items)				
(b) Indigenous* (specify items)				
(c) Container				
(d) Other packing materials				
TOTAL				
(ii) Conversion charges (inclusive of processing, quality control, packing and depreciation; indicate basis, if necessary in a separate sheet)				
(iii) Royalty and service fees, if any.				
(iv) Excise duty				
Ex-factory Cost				
C. Promotion and distribution expenses (indicate, if necessary on a separate sheet the basis on which the incidence has been arrived at)				
D. Profit (indicate, if necessary on a separate sheet the basis on which the incidence has been arrived at).				
TOTAL				
E. Selling commission				
F. Wholesale price				
G. Retailers margin				
H. Retail price				

*In the case of imported and indigenous raw materials please furnish particulars in Part IV.

PART IV

Break up of Material cost to Factory

(a) *Imported materials*

Description of material	Unit	CIF	Customs duty	Clearing and other charges	Cost to factory
		Rs.	Rs.	Rs.	Rs.

(b) *Indigenous materials*

Description of material	Unit	Basic price	Sales Tax and Octroi	Transport charges	Cost to factory
		Rs.	Rs.	Rs.	Rs.

Signature of the Manufacturer,
Importer or Distributor of drugs"

[No. 18-13/66-Ch. III]

M RAMAKRISHNAYYA, Jt Secy

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